



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/647,657

08/25/2003

William Cohn

BIH-002AX

2131

207 7590 01/18/2011
WEINGARTEN, SCHURGIN, GAGNEBIN & LEOVICI LLP
TEN POST OFFICE SQUARE
BOSTON, MA 02109

EXAMINER

BACHMAN, LINDSEY MICHELE

ART UNIT

PAPER NUMBER

3734

MAIL DATE

DELIVERY MODE

01/18/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/647,657	Applicant(s) COHN ET AL.	
	Examiner LINDSEY BACHMAN	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 November 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11-24-10</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is in response to Applicant's amendment filed 24 November 2010.

Response to Arguments

Applicant's arguments filed 24 November 2010 have been fully considered but they are not persuasive.

Applicant argues that the suture and needle system of SU'696 is not disclosed for joining a heart valve to tissue. Examiner agrees. However, the claims are rejected with a 103 rejection and Examiner maintains that Phillips'965 teaches the use of a suture and needle system to attach a heart valve to tissue. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant argues that the Office Action states that attaching two tissue layers is identical to attaching to joining a valve to tissue. The Office Action did not say that, however similar considerations would be made when joining both tissue to tissue and tissue to a heart valve: attaching speed, minimizing the number of stitches made while maximizing the strength of the attachment, etc. As such, it would be obvious to modify the Phillips'965 as taught by SU'696.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10, 11, 14 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 10, 11 and 14 recite the limitation "the prosthetic device". There is insufficient antecedent basis for this limitation in the claim. In the most recent amendment, Applicant amended independent claim 5, from which Claims 10, 11 and 14 depend, to remove the term "prosthetic device" and replace it with the term "a heart valve", creating these lack of antecedent basis issues.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-8, 10, 11, 14, 16-18, 20-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Phillips'965 in view of Soviet Union Patent 513696 (SU'696).

Claim 1-4, 20-23, 25-28: Phillips'965 teaches a method of implanting an artificial valve including placing a first suture (26) through tissue (40) at a first position using a first needle (32); placing a second needle (34) through tissue (40) at a second position, and repeating this processes using additional needles. The prosthetic device (16) is

Art Unit: 3734

attached to the annulus body tissue (40) using needles in the suturing system and is then secured to the body (column 2, lines 15-46). Phillips'965 teaches color-coding to identify different threads (column 1, lines 23-57 and column 2, lines 40-44). Phillips does not teach using a suture system that contains more than three needles connected by suture strands.

SU'696 teaches suture system that contains three needles (2) connected by suture strands (5, 6, 7, 8) that are spread apart by a pre-determined length of suture. SU'696 teaches that it is well-known to use a system like this when attaching two biomaterials (shown in figure, but unlabeled) because it reduces the time needed to apply several stitches because there are fewer needle insertions and it makes the joint created with the sutures stronger because there are no sectors between the adjacent knot stitches (Derwent abstract). It would have been obvious one of ordinary skill in the art to modify the suture/needle combination taught by Phillips'965 by attaching two different suture strands to a single needle and creating a multi-needle and suture system as taught by SU'696 because of the advantages disclosed by SU'696. This combination would result in the claimed invention because Phillips'965 is teaching different colored sutures and attaching a single suture to two needles and SU'696 teaches that it is advantageous to connect multiple needles together to create separate sutures (by cutting after deployment).

Although Phillips'965 in view of SU'696 does not specifically teach the use of more than three needles, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use more than three needles, since it has

Art Unit: 3734

been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Regarding Claim 1 and 21 and the limitation about the diameter of the needle being larger than the diameter of the suture strands, it has been held that to be entitled to weight in method claims, the recited structure limitations therein must affect the method in a manipulative sense, and not to amount to the mere claiming of a use of a particular structure. *Ex parte Pfeiffer*, 1962 C.D. 408 (1961). Further, It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the diameter of the needle relative to the diameter of the sutures, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Claims 5, 6, 8, 29, 30, 31, 32, 33, 34: Phillips teaches the use of a number of suture and needle sets that each contain a single suture (26) attached to two separate needles (32, 34) at opposite ends of the suture. Each suture and needle set (combination of suture 26 and needles 32, 34) contain a different color suture (column 1, lines 23-57 and column 2, lines 40-44). Phillips'965 does not teach the use of a single device having more than three needles with at least one needle attached to two separate sutures.

SU'696 teaches a suturing device containing at least three needles (2) with at least one needle having two suture strand sections (6, 7) extending from the needle; each suture strand extends between a pair of connected needles. The needles (2) are

Art Unit: 3734

removable from the suture strands (Derwent Abstract, line 5). Further, the first end needle of SU'696 is attached to a single suture strand section and the second end needle is attached to at least a single suture strand section (see Figure in SU'696). SU'696 teaches that it is well-known to use a system having a single needle attached to two suture strand sections for attaching two biomaterials (shown in figure, but unlabeled) because it reduces the time needed to apply several stitches since there are fewer needle insertions. SU'696 further teaches that it makes the joint created with the sutures stronger because there are no sectors between the adjacent knot stitches (Derwent abstract). It would have been obvious one of ordinary skill in the art to modify the suture/needle combination taught by Phillips'965 by attaching two different sutures to a single needle because of the advantages disclosed by SU'696.

Although Phillips'965 in view of SU'696 does not specifically teach the use of more than three needles, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use more than three needles, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Claim 7: SU'696 teaches that suturing device contains three needles (2) that are associated with at least two sutures strands (5, 6, 7, 8; best shown in SU'696's figure).

Claims 10, 11, and 14: Phillips'965 teaches a cuff (16) through which sutures (26) are threaded (column 2, lines 16-32) during aortic valve replacement surgery (column 1, lines 1-20). The cuff is threaded before surgery to reduce implantation time (column 1, lines 23-42). Therefore it would have been obvious to one skilled in the art at

Art Unit: 3734

the time the invention was made to use the device taught by Phillips'965 and SU'696 to suture a cuff prior to surgery in order to reduce implantation time and reduce the risks of the surgery.

Claim 16: Phillips'965 teaches passing sutures through both the cuff (18) and the valve (12).

Claim 17: Philips'965 teaches the method substantially as claimed, except for passing different strands attached to the same needle through the same hole in the tissue. SU'696 teaches passing different suture strands attached to the same needle through the same hole because it reduces the time needed to apply several stitches because there are fewer needle insertions and it makes the joint created with the sutures stronger because there are no sectors between the adjacent knot stitches (Derwent abstract). It would have been obvious one of ordinary skill in the art to substitute the suture/needle combination taught by Phillips'965 with the suture system taught by SU'696 because the results of the substitution would have been predicable and superior to the system taught by Phillips since the system taught by SU'696 is faster to use and creates stronger joints. Regarding the limitation about the diameter of the needle being larger than the diameter of the suture strands, it has been held that to be entitled to weight in method claims, the recited structure limitations therein must affect the method in a manipulative sense, and not to amount to the mere claiming of a use of a particular structure. *Ex parte Pfeiffer*, 1962 C.D. 408 (1961).

Claim 18: Phillips'965 teaches attaching a valve (column 1, lines 5-20).

Claim 24: Philips'965 in view of SU'696 does not teach the use of 6 needles. However, since SU'696 teaches 3 needles connected in series, and a device containing 6 needles connected in series would perform equally as well as 3 needles, it would be an obvious matter of design choice to vary the number of needles depending on the size of the length of the objected being sutured together.

Further, although Phillips'965 in view of SU'696 does not specifically teach the use of more than three needles, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use more than three needles, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Claims 9 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Phillips'965 in view of SU'696, as applied to Claim 5, and further in view of Ablaza (US Patent 4,632,113).

Claim 9, 15: Phillips'965 in view of SU'696 teach the limitations of Claim 9, except for the use of suture pads.

Ablaza'113 teaches the use of suture pads (12 in Figure 1, or 20 in Figure 2) attached to suture strands (18) because they prevent any movement between the suture and the pad, and reduce the tendency of the suture to tangle; further, Ablaza'113 teaches that suture pads are used as anchors when the suturing device is used to close a slit in an aorta (column 2, lines 63-68 and column 3, lines 1-8). It would have been obvious to one skilled in the art at the time the invention was made to modify the device

Art Unit: 3734

taught by Phillips'965 and SU'696 with a suture pad because they allow the suture to act as an anchor when closing the aorta.

Claim 12 rejected under 35 U.S.C. 103(a) as being unpatentable over Phillips'965 in view of SU'696, as applied to Claim 5, and in further view of Alpern, et al. (US Patent 5,284,293).

Phillips'965 in view of SU'696 teach the limitations of Claim 12, except for the use of a package for housing the suture device. Alpern'293 teaches that it is well known in the art to use a dispenser to house suturing devices prior to use because they are packaged in a sterile manner and it is beneficial to be able to see the quantity of suturing devices in a box (column 1, lines 1-34). It would have been obvious to one skilled in the art at the time the invention was made to place sterile packaged sutures in a box prior to use because this makes it easier for doctors to see the quantity of suturing devices in the box.

Claim 13 rejected under 35 U.S.C. 103(a) as being unpatentable over Phillips'965 in view of SU'696, as applied to Claim 5, and in further view of Ovil, et al. (US Patent 4,702,250).

Phillips'965 in view of SU'696 teach the limitations of Claim 13, except for a mechanical suture placement device.

Mechanical suture placement devices are well known in the art and it would have been obvious to include a mechanical suture placement device to place the sutures. Furthermore, Ovil'250 teaches the use of a mechanical suture placement apparatus because suture placement is time consuming and there is a risk of entangling the

Art Unit: 3734

sutures. It would have been obvious to one skilled in the art at the time the invention was made to use a mechanical suture placement device to place the sutures because it is easier for the surgeon and reduces the risk of entanglement.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over SU'696 and Phillips'965 and SU'696, as applied to Claim 1, and in further view of Alpern, et al. (US Patent 5,284,293).

Phillips'965 and SU'696 teach the limitations of Claim 19, except for the use of a package for housing the suture device. Alpern'293 teaches that it is well known in the art to use a dispenser to house suturing devices prior to use because they are packaged in a sterile manner and it is beneficial to be able to see the quantity of suturing devices in a box (column 1, lines 1-34). Therefore it would have been obvious to one skilled in the art at the time the invention was made to place sterile packaged sutures taught by Phillips'965 and SU'696 in a box, as taught by Alpern'293, prior to use because this makes it easier for doctors to see the quantity of suturing devices in the box.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LINDSEY BACHMAN whose telephone number is (571)272-6208. The examiner can normally be reached on Monday to Thursday 7:30 am to 5 pm, and alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3734

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/L. B./

Examiner, Art Unit 3734

/TODD E. MANAHAN/

Supervisory Patent Examiner, Art Unit 3776